
API Regulatory Affairs
Drug Product Regulatory Affairs
API Services
New Molecule Development
Analytical Services
Drug Product Services
Edelweiss Medica
L'excellence par la science
Reference Materials
Preformulation Studies
Clinical Services
Medical Devices
Formulation Development
Reformulation Studies

Our mission is to provide pharmaceutical regulatory and development services to pharmaceutical companies. We aim to provide R & D and regulatory support at all development stages of active pharmaceutical ingredients and finished formulations, for health markets around the world. By partnering with CDMOs / CROs, analytical development labs and highly experienced consultants and scientists, we provide world-class R & D and regulatory services at reasonable costs to our clients. Our professional expertise will enable our clients to successfully launch new products or update regulatory dossiers in a timely manner. We believe that our services will ultimately contribute to the betterment of patient's health, when the pharmaceutical products of our clients are marketed.

Services offered

CMC Regulatory Affairs

API regulatory Affairs

- Regulatory dossier (US DMF, ASMF, CEP, eCTD) authoring for new products
- Life-cycle maintenance, including pharmacopoeial updates
- Regulatory strategy, ICH M7 assessment
- Change-control assessment
- DMF updates and annual reports
- Gap analysis, elemental and nitrosamine risk assessment
- CEP variations
- Responding to deficiency letters from regulatory authorities

Drug Product Regulatory Affairs

- Regulatory dossier (US, EU and eCTD) authoring for new products
- Life-cycle maintenance: Variations (EU and US) and annual updates
- Regulatory strategy
- Change-control assessment
- USFDA: Abbreviated New Drug applications (ANDA)
- EU: National, Mutual Recognition Procedure (MRP), Decentralised Procedure (DCP) and Centralised Procedure (CP)
- Gap analysis, elemental and nitrosamine risk assessment
- Responding to request for information (RFI)

Medical Devices

- Support for approval of new product
- Review of EU technical files
- GAP analysis
- IFU – Instructions For Use
- Support MDR and IVDR regulation
- Labelling compliance
- UDI – Unique Device Identification
- Support for UKCA marking
- Preparation and management of technical documentation according to GSPR
- EU authorised representative service

API Services

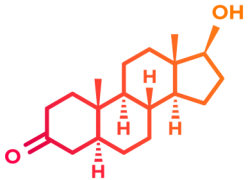
API Development

- Route-scouting
- Reaction optimisation
- Process validation / qualification
- Synthesis and characterisation of impurities
- Characterisation
- Setting of specifications
- Development services based on ICH Q11 guidelines
- M7 assessment based on QSAR reports
- Nitrosamine risk assessment
- Stress studies
- Stability studies
- Accelerated stability studies
- Polymorphism
- Hygroscopicity
- Physicochemical properties

New molecule development

- CRAMS (Contract Research and Manufacturing Service)
- Synthesis of compound libraries
- Synthesis of impurities
- Selection of candidate molecule(s)
- Scale-up for early pre-clinical development
- Scale-up for first-in-man studies

TESTOSTERONE



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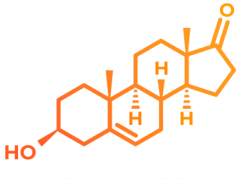

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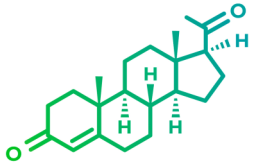


PROGESTERONE

Drug Product Services

By applying the principles of Quality-by-Design (QBD), we partner with formulation experts to develop several conventional and specialised dosage forms. We provide support at all stages of drug development to find a suitable dosage form to suit your marketing needs. Our Drug Product Development services are listed below.

Pre-formulation studies

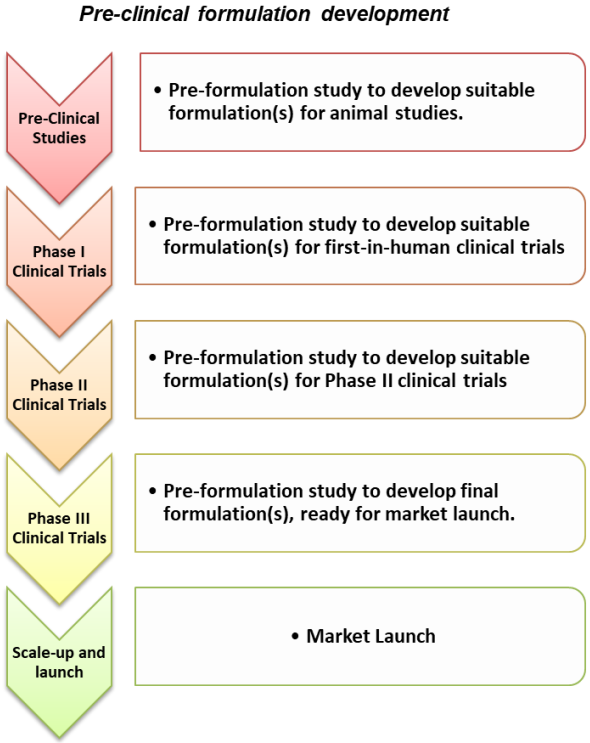
Robust pre-formulation studies are essential for successful development of dosage form(s) to suit the intended purpose at pre-clinical or clinical stage(s).

Re-formulations studies

- Excipient compatibility
- Stress studies
- Stability studies
- Accelerated stability studies
- Polymorphism
- Dissolution
- Hygroscopicity
- Physicochemical properties (eg. Solubility, bulk and tapped density)

Formulation Development

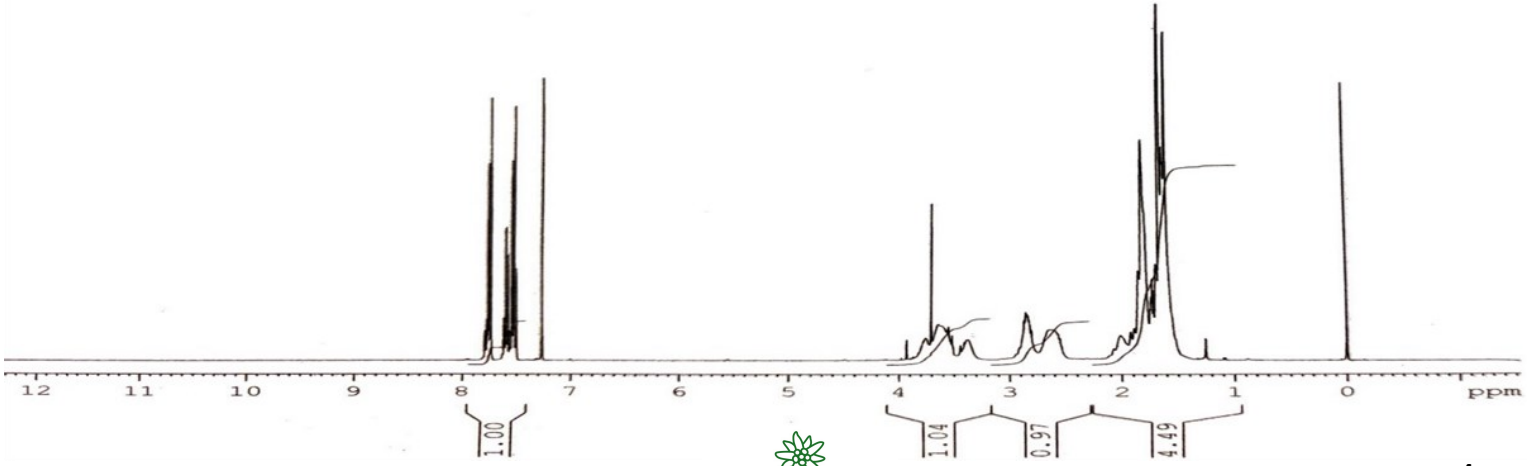
- IR tablets
- MR / CR tablets
- IR capsules
- MR / CR capsules
- Oral solutions, suspensions and powders for reconstitution
- Effervescent tablets and powders



Analytical Services

Analytical development services for both active pharmaceutical ingredients and drug products.

- Full analytical method validation for assay, related substances and residual solvents. Typical instruments used: HPLC, GC, GC-MS, LCMS, potentiometry, UV-Visible spectroscopy, Polarimetry, NMR).
- Analytical method transfer.
- Monograph method verification (eg. Ph. Eur and USP) and comparison.
- Gap analysis and finding solutions for deficiencies in currently approved methods.



Regulatory Strategy

Regulatory strategy for both APIs (DMF, ASMF, CEP, JMF) and marketing authorisation for drug products.

- DMF registration
- Certificate of suitability (CEP)
- Legal basis of MA application based on EU Directive 2001/83/EC.
- Generic medicinal drug product application – Art. 10(1)
- Hybrid medicinal drug product application – Art. 10(3)
- Bio-similar drug product application – Art. 10(4)
- Well established use application based on literature – Art 10a
- Combination dosage forms application – Art. 10b
- Selection of Reference Medicinal Product (RMP)
- Identifying suitable Reference Member State (RMS)
- USFDA: ANDA, BLA application
- UK MHRA MA applications
- Brazil – ANVISA
- MA application support for other territories include: Japan, Brazil, Canada, Australia, Taiwan and rest of the world
- Market feasibility study
- Change-control assessment and classification of variations
- Support with post-approval change management protocols. With an approved change management protocol, the change can typically be classified as at least one category lower than the actual variation category described in the EU variation guidelines.
- Support with strategy to identify and qualify new suppliers of APIs, raw materials for drug products and reagents / starting materials/ intermediates for API synthesis.

Regulatory labelling

- Patient information leaflet (PIL)
- User testing of patient information leaflet
- Summary of product characteristics (SmPC)
- Leaflet mock-up design

Regulatory Training

Regulatory training on ICH, US FDA, and Ph. Eur. Guidelines.

API and drug product Regulatory Affairs

* Selection of raw materials, starting materials and intermediates.
* Impurities / related-substances, residual solvents and elemental impurities.
* Setting specifications
* ICH M7 assessment
* Stability testing, accelerated stability studies, photostability, evaluation of stability data, Stability conditions for different climatic zones
* GMP guidelines
* USFDA ANDA and BLA applications
* EU MA applications: National, MRP, DCP, CP and orphan drugs
* EU variation guidelines and US Scale Up, Post Approval Changes guidelines (SUPAC)
* Concept of bioequivalence
* Biopharmaceutics classification system (BCS)
* Dissolution and disintegration
* Pharmaceutical drug product development
* EU Legal basis of marketing authorisation
* Analytical method validation
* USFDA ANDA and BLA applications
* EU MA applications: National, MRP, DCP, CP and orphan drugs

- BA/BE studies for EU generics and US ANDA applications
- Small and large molecule BA/BE studies
- In-vitro / in-vivo correlation (IVIVC)
- Comparative BA/BE study
- Study fasting and fed conditions on BA/BE
- BA/BE studies for immediate release (IR) and modified / Controlled release (MR/CR) formulations
- BA/BE studies for different routes of administration
- Setting up study design
- Preparation of study protocols
- Independent Ethics Committee – Review and Management

Reference Materials

Package Design

- Supply reference standards of APIs and impurities.
- Supply of Reference Medicinal Product(s) to aid the development of generic equivalents
- Our experts can design high quality pharmaceutical packaging artworks for medicinal products and medical devices

Sourcing of APIs, Intermediates and Generic Drug Formulations

- With our global network, we can source intermediates and raw materials necessary for your API synthesis.
- Sourcing of high quality cGMP API materials to meet you specifications. We can also help you to identify and qualify alternative sources of APIs to avoid shortages. Generic APIs with EU CEPs or DMFs for EU, US, and Japan are available
- Sourcing of finished generic drug products. Products available for in-licencing, out-licencing and MA transfers.

Translation Services

Translations from English to European languages and from European languages to English.
Examples of documents we can translate are given below.

- Master Batch Records (MBRs)
- Executed Batch Records
- Validation Protocols
- Validation Reports
- Analytical Methods
- Annual Product Quality Reviews
- Change Controls

Contact us for further details and list of available products.

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